

Declaration of Conformity
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES



MANUFACTURER:

Weihai Weigao Blood Purification Products Co., Ltd.

No.20 Xingshan Road, Weihai Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, PEOPLE'S
REPUBLIC OF CHINA

MEDICAL DEVICE:

A.V. Fistula Needle Sets

MODEL: 1.4×25GD, 1.4×25XD, 1.4×32GD, 1.4×32XD, 1.6×25GD, 1.6×25XD, 1.6×32GD, 1.6×32XD, 1.8×
25GD, 1.8×25XD, 1.8×32GD, 1.8×32XD, 1.4×25GS, 1.4×25XS, 1.4×32GS, 1.4×32XS, 1.6×25GS, 1.6×25XS,
1.6×32GS, 1.6×32XS, 1.8×25GS, 1.8×25XS, 1.8×32GS, 1.8×32XS

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 7

CONFORMITY ASSESSMENT ROUTE:

ANNEX II .3

WE, Weihai Weigao Blood Purification Products Co., Ltd. HEREWITH DECLARE THAT THE STATED MEDICAL
DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURERS. THE
MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

ZERTIFIZIERSTELLE RIDLERSTR. 65·80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G1 076229 0004 REV.01



EUROPEAN REPRESENTATIVE:

MedNet GmbH

Borkstrasse 10, 48163 Muenster, GERMANY.

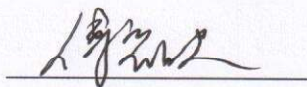
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START OF CE-MARKING: 2018.11.29

VALID UNTIL : 2021.11.14

PLACE, DATE OF DECLARATION: CITY, DATE (WEIHAI, 2018.11.29)

SIGNATURE:



NAME: Mr. YINBO FU

POSITION: Vice Quality Director